IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, v. TEVA PARENTERAL MEDICINES, INC., APP PHARMACEUTICALS, LLC, PLIVA HRVATSKA D.O.O., TEVA PHARMACEUTICALS USA, INC., and BARR LABORATORIES, INC., Defendants.	)	Civil Action No. 1:10-cv-01376-TWP-DKL (consolidated with 1:11-cv-0942)

AMENDED COMPLAINT

Plaintiff Eli Lilly and Company ("Lilly"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filings by Defendant Teva Parenteral Medicines, Inc. ("Teva"), APP Pharmaceuticals, LLC ("APP"), Pliva Hrvatska d.o.o. ("Pliva Hrvatska"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Barr Laboratories, Inc. ("Barr") (Barr, together with Pliva Hrvatska and Teva USA, are referred to herein as "Pliva") of Abbreviated New Drug Applications ("ANDAs") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of ALIMTA® prior to the expiration of U.S. Patent No. 7,772,209.

PARTIES

2. Lilly is a corporation organized and existing under the laws of the State of Indiana, having its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

3. Upon information and belief, defendant Teva is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 19 Hughes, Irvine, California 92618.

4. Upon information and belief, defendant APP is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173-5837.

5. Upon information and belief, defendant Pliva Hrvatksa is a corporation organized and existing under the laws of the Republic of Croatia, having its principal place of business at Ulica grada Vukovara 49, HR-10000, Zagreb, Croatia.

6. Upon information and belief, defendant Teva USA is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

7. Upon information and belief, defendant Barr is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 225 Summit Avenue, Montvale, New Jersey 07645.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

10. Upon information and belief, Teva is subject to personal jurisdiction in this District because, among other things, Teva markets, sells, and distributes generic drugs throughout the United States, including within the State of Indiana and the Southern District of Indiana. Upon information and belief, Teva has engaged in and maintained systematic and continuous business contacts within the State of Indiana and the Southern District of Indiana, and has purposefully availed itself of the benefits and protections of the laws of Indiana.

11. Upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of Teva's ANDA Nos. 90-352 and/or 90-674 for generic versions of ALIMTA®, Teva (directly or through Teva USA) will market, distribute, and sell its generic products throughout the United States and within Indiana and the Southern District of Indiana, and knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana. Upon information and belief, following any FDA approval of ANDA Nos. 90-352 and/or 90-674, Teva knows and intends that its generic products will be marketed, distributed, and sold in the United States and within the State of Indiana and the Southern District of Indiana, and knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana.

12. Upon information and belief, APP is subject to personal jurisdiction in this District because, among other things, APP markets, sells, and distributes generic drugs throughout the United States, including within the State of Indiana and the Southern District of Indiana. Upon information and belief, APP has engaged in and maintained systematic and continuous business contacts within the State of Indiana and the Southern District of Indiana, and has purposefully availed itself of the benefits and protections of the laws of Indiana.

13. Upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of APP's ANDA No. 90-384 for generic versions of ALIMTA®, APP will market, distribute, and sell its generic products throughout the United States and within Indiana and the Southern District of Indiana, and knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana. Upon information and belief, following any FDA approval of ANDA No. 90-384, APP knows and intends that its generic products will be marketed, distributed, and sold in the United States and within the State of Indiana and the Southern District of Indiana, and knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana.

14. Upon information and belief, Pliva Hrvatska is subject to personal jurisdiction in this District because, among other things, Pliva Hrvatska, directly or through an agent and/or alter ego, markets, sells, and distributes generic drugs throughout the United States, including within the State of Indiana and the Southern District of Indiana. Upon information and belief, Pliva Hrvatska has engaged in and maintained systematic and continuous business contacts within the State of Indiana and the Southern District of Indiana, and has purposefully availed itself of the benefits and protections of the laws of Indiana.

15. Upon information and belief, Teva USA is subject to personal jurisdiction in this District because, among other things, Teva USA markets, sells, and distributes generic drugs throughout the United States, including within the State of Indiana and the Southern District of Indiana. Upon information and belief, Teva USA has engaged in and maintained systematic and continuous business contacts within the State of Indiana and the Southern District of Indiana, and has purposefully availed itself of the benefits and protections of the laws of Indiana.

16. Upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of Teva's ANDA Nos. 90-352 and/or 90-674 for generic versions of ALIMTA®, Teva USA will market, distribute, and sell Teva's generic products throughout the United States and within Indiana and the Southern District of Indiana, and knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana.

17. Upon information and belief, Barr is subject to personal jurisdiction in Indiana because, among other things, Barr markets, sells, and distributes generic drugs throughout the United States, including within the State of Indiana and the Southern District of Indiana. Upon information and belief, Barr has engaged in and maintained systematic and continuous business contacts within the State of Indiana and the Southern District of Indiana, and has purposefully availed itself of the benefits and protections of the laws of Indiana.

18. Upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of Pliva's ANDA No. 091111 for a generic version of ALIMTA®, Pliva will (directly through Pliva Hrvatska, through Teva USA or Barr, or through an agent and/or alter ego) market, distribute, and sell its generic product throughout the United States and within Indiana and the Southern District of Indiana. Upon information and belief, following any FDA approval of ANDA No. 091111, Pliva knows and intends that its generic products will be marketed, distributed, and sold in the United States and within the State of Indiana and the Southern District of Indiana, and knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana.

BACKGROUND

19. ALIMTA® is a chemotherapy drug used for the treatment of various types of cancer. ALIMTA® is indicated (in combination with cisplatin) (a) for the treatment of patients with malignant pleural mesothelioma, or (b) for the initial treatment of locally advanced or metastatic nonsquamous non-small cell lung cancer. ALIMTA® also is indicated as a single-agent for the treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy. ALIMTA® also is indicated for maintenance treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.

20. Lilly sells ALIMTA® in the United States pursuant to a New Drug Application that has been approved by the FDA.

21. United States Patent No.7,772,209 ("the '209 patent"), entitled "Novel Antifolate Combination Therapies", was duly and legally issued on August 10, 2010. The '209 patent is attached as Exhibit A hereto.

22. Lilly is the assignee of the '209 patent. As set forth in greater detail in the '209 patent, one or more claims of the '209 patent, incorporated by reference herein, cover a method of administering pemetrexed disodium to a patient in need thereof that also involves administration of folic acid and vitamin B_{12}.

COUNT I

(Patent Infringement – Teva's ANDA No. 90-352 (500 mg))

23. Lilly incorporates each of the preceding paragraphs as if fully set forth herein.

24. By letter dated April 24, 2008, Teva notified Lilly that it had submitted to the FDA ANDA No. 90-352 for Teva's Pemetrexed Disodium for Injection, Eq. 500 mg Base/Vial product ("Teva's 500 mg ANDA Product"). Teva's 500 mg ANDA Product is a generic version of ALIMTA®.

25. The purpose of ANDA No. 90-352 was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's 500 mg ANDA Product prior to the expiration of U.S. Patent No. 5,344,932 ("the '932 patent"). The expiration date of the '932 patent is earlier than the expiration date of the '209 patent.

26. In the April 24, 2008 letter, Teva notified Lilly that Teva's 500 mg ANDA Product contains pemetrexed disodium.

27. Upon information and belief, the use of Teva's 500 mg ANDA Product in accordance with Teva's proposed labeling for Teva's 500 mg ANDA Product involves administration of folic acid and vitamin B_{12}.

28. By letter dated September 17, 2010 ("the Teva 2010 500 mg Notice Letter"), Teva again notified Lilly that it had submitted to the FDA ANDA No. 90-352 for Teva's 500 mg ANDA Product.

29. In the Teva 2010 500 mg Notice Letter, Teva also notified Lilly that, as part of its ANDA No. 90-352, Teva had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '209

patent. Upon information and belief, Teva submitted ANDA No. 90-352 containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '209 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of Teva's 500 mg ANDA Product. The submission of ANDA No. 90-352 with such a certification for the '209 patent is an act of infringement of the '209 patent.

30. Upon information and belief, the use of Teva's 500 mg ANDA Product in accordance with and as directed by Teva's proposed labeling for that product will infringe one or more claims of the '209 patent.

31. Teva's submission of ANDA No. 90-352 is for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's 500 mg ANDA Product prior to the expiration of the '209 patent.

32. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's 500 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-352, *i.e.*, prior to the expiration of the '209 patent.

33. On July 31, 2012, counsel for Teva USA notified Lilly that Teva USA may distribute or sell the products that are the subject of "the [Teva Parenteral Medicines] ANDA." Upon information and belief, Teva USA intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's 500 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-352, *i.e.*, prior to the expiration of the '209 patent.

34. Upon information and belief, Teva and Teva USA have knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Teva and Teva USA have continued

to assert their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's 500 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-352.

35. Upon information and belief, Teva and Teva USA plan and intend to, and will, actively induce infringement of the '209 patent when ANDA No. 90-352 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

36. Upon information and belief, Teva and Teva USA know that Teva's 500 mg ANDA Product is especially made or adapted for use in infringing the '209 patent, and that Teva's 500 mg ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Teva and Teva USA plan and intend to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 90-352.

37. The foregoing actions by Teva and/or Teva USA constitute and/or will constitute infringement of the '209 patent, active inducement of infringement of the '209 patent, and contribution to the infringement by others of the '209 patent.

38. Upon information and belief, Teva and Teva USA are without a reasonable basis for believing that they will not be liable for infringing the '209 patent, actively inducing infringement of the '209 patent, and/or contributing to the infringement by others of the '209 patent.

39. Unless Teva and Teva USA are enjoined from infringing the '209 patent, actively inducing infringement of the '209 patent, and contributing to the infringement by others of the '209 patent, Lilly will suffer irreparable injury. Lilly has no adequate remedy at law.

40. An actual case or controversy exists between Lilly and Teva, and between Lilly and Teva USA, with respect to infringement of the '209 patent.

COUNT II

(Patent Infringement – Teva's ANDA No. 90-674 (100 mg))

41. Lilly incorporates each of the preceding paragraphs as if fully set forth herein.

42. By letter dated October 14, 2008, Teva notified Lilly that it had submitted to the FDA ANDA No. 90-674 for Teva's Pemetrexed Disodium for Injection, Eq. 100 mg Base/Vial product ("Teva's 100 mg ANDA Product"). Teva's 100 mg ANDA Product is a generic version of ALIMTA®.

43. The purpose of ANDA No. 90-674 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's 100 mg ANDA Product prior to the expiration of the '932 patent. The expiration date of the '932 patent is earlier than the expiration date of the '209 patent.

44. In the October 14, 2008 letter, Teva notified Lilly that Teva's 100 mg ANDA Product contains pemetrexed disodium.

45. Upon information and belief, the use of Teva's 100 mg ANDA Product in accordance with Teva's proposed labeling for Teva's 100 mg ANDA Product involves administration of folic acid and vitamin B_{12}.

46. By letter dated September 17, 2010 ("the Teva 2010 100 mg Notice Letter"), Teva again notified Lilly that it had submitted to the FDA ANDA No. 90-674 for Teva's 100 mg ANDA Product.

47. In the Teva 2010 100 mg Notice Letter, Teva also notified Lilly that, as part of its ANDA No. 90-674, Teva had filed a certification of the type described in Section

505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '209 patent. Upon information and belief, Teva submitted ANDA No. 90-674 containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '209 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of Teva's 100 mg ANDA Product. The submission of ANDA No. 90-674 with such a certification for the '209 patent is an act of infringement of the '209 patent.

48. Upon information and belief, the use of Teva's 100 mg ANDA Product in accordance with and as directed by Teva's proposed labeling for that product will infringe one or more claims of the '209 patent.

49. Teva's submission of ANDA No. 90-674 is for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's 100 mg ANDA Product prior to the expiration of the '209 patent.

50. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's 100 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-674, *i.e.*, prior to the expiration of the '209 patent.

51. On July 31, 2012, counsel for Teva USA notified Lilly that Teva USA may distribute or sell the products that are the subject of "the [Teva Parenteral Medicines] ANDA." Upon information and belief, Teva USA intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's 100 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-674, *i.e.*, prior to the expiration of the '209 patent.

52. Upon information and belief, Teva and Teva USA have knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Teva and Teva USA have continued to assert their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's 100 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-674.

53. Upon information and belief, Teva and Teva USA plan and intend to, and will, actively induce infringement of the '209 patent when ANDA No. 90-674 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

54. Upon information and belief, Teva and Teva USA know that Teva's 100 mg ANDA Product is especially made or adapted for use in infringing the '209 patent, and that Teva's 100 mg ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Teva and Teva USA plan and intend to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 90-674.

55. The foregoing actions by Teva and/or Teva USA constitute and/or will constitute infringement of the '209 patent, active inducement of infringement of the '209 patent, and contribution to the infringement by others of the '209 patent.

56. Upon information and belief, Teva and Teva USA are without a reasonable basis for believing that they will not be liable for infringing the '209 patent, actively inducing infringement of the '209 patent, and/or contributing to the infringement by others of the '209 patent.

57. Unless Teva and Teva USA are enjoined from infringing the '209 patent, actively inducing infringement of the '209 patent, and contributing to the infringement by others of the '209 patent, Lilly will suffer irreparable injury. Lilly has no adequate remedy at law.

58. An actual case or controversy exists between Lilly and Teva, and between Lilly and Teva USA, with respect to infringement of the '209 patent.

COUNT III

(Patent Infringement – APP's 500 mg ANDA Product)

59. Lilly incorporates each of the preceding paragraphs as if fully set forth herein.

60. By letters dated June 10, 2008 ("APP's 2008 Notice Letter") and June 2, 2011 ("APP's 500 mg Notice Letter"), APP notified Lilly that it had submitted to the FDA ANDA No. 90-384 for APP's Pemetrexed Disodium Injectable, Eq. 500 mg Base/Vial product ("APP's 500 mg ANDA Product").

61. APP's 500 mg ANDA Product is a generic version of ALIMTA®.

62. The purpose of ANDA No. 90-384 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of APP's 500 mg ANDA Product prior to the expiration of the '209 patent.

63. In APP's 2008 Notice Letter and APP's 500 mg Notice Letter, APP notified Lilly that APP's 500 mg ANDA Product contains pemetrexed disodium.

64. Upon information and belief, the use of APP's 500 mg ANDA Product in accordance with APP's proposed labeling for APP's 500 mg ANDA Product involves administration of folic acid and vitamin B_{12}.

65. Upon information and belief, the use of APP's 500 mg ANDA Product in accordance with and as directed by APP's proposed labeling for that product will infringe one or more claims of the '209 patent.

66. APP's submission of ANDA No. 90-384 is for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of APP's 500 mg ANDA Product prior to the expiration of the '209 patent.

67. Upon information and belief, APP intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's 500 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384, *i.e.*, prior to the expiration of the '209 patent.

68. Upon information and belief, APP has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, APP has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's 500 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384.

69. Upon information and belief, APP plans and intends to, and will, actively induce infringement of the '209 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

70. Upon information and belief, APP knows that APP's 500 mg ANDA Product is especially made or adapted for use in infringing the '209 patent, and that APP's 500 mg ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, APP plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 90-384.

71. The foregoing actions by APP constitute and/or will constitute infringement of the '209 patent, active inducement of infringement of the '209 patent, and contribution to the infringement by others of the '209 patent.

72. Upon information and belief, APP is without a reasonable basis for believing that it will not be liable for infringing the '209 patent, actively inducing infringement of the '209 patent, and/or contributing to the infringement by others of the '209 patent.

73. Unless APP is enjoined from infringing the '209 patent, actively inducing infringement of the '209 patent, and contributing to the infringement by others of the '209 patent, Lilly will suffer irreparable injury. Lilly has no adequate remedy at law.

74. An actual case or controversy exists between Lilly and APP with respect to infringement of the '209 patent.

COUNT IV

(Patent Infringement – APP's 100 mg ANDA Product)

75. Lilly incorporates each of the preceding paragraphs as if fully set forth herein.

76. By a letter dated June 2, 2011 ("APP's 100 mg Notice Letter"), APP notified Lilly that it had submitted to the FDA a Supplement to ANDA No. 90-384 for APP's Pemetrexed Disodium Injectable, Eq. 100 mg Base/Vial product ("APP's 100 mg ANDA Product").

77. APP's 100 mg ANDA Product is a generic version of ALIMTA®.

78. The purpose of ANDA No. 90-384 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of APP's 100 mg ANDA Product prior to the expiration of the '209 patent.

79. In APP's 100 mg Notice Letter, APP notified Lilly that APP's 100 mg ANDA Product contains pemetrexed disodium.

80. Upon information and belief, the use of APP's 100 mg ANDA Product in accordance with APP's proposed labeling for APP's 100 mg ANDA Product involves administration of folic acid and vitamin B_{12}.

81. Upon information and belief, the use of APP's 100 mg ANDA Product in accordance with and as directed by APP's proposed labeling for that product will infringe one or more claims of the '209 patent.

82. APP's submission of ANDA No. 90-384 is for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of APP's 100 mg ANDA Product prior to the expiration of the '209 patent.

83. Upon information and belief, APP intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's 100 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384, *i.e.*, prior to the expiration of the '209 patent.

84. Upon information and belief, APP has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, APP has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's 100 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384.

85. Upon information and belief, APP plans and intends to, and will, actively induce infringement of the '209 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

86. Upon information and belief, APP knows that APP's 100 mg ANDA Product is especially made or adapted for use in infringing the '209 patent, and that APP's 100 mg ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, APP plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 90-384.

87. The foregoing actions by APP constitute and/or will constitute infringement of the '209 patent, active inducement of infringement of the '209 patent, and contribution to the infringement by others of the '209 patent.

88. Upon information and belief, APP is without a reasonable basis for believing that it will not be liable for infringing the '209 patent, actively inducing infringement of the '209 patent, and/or contributing to the infringement by others of the '209 patent.

89. Unless APP is enjoined from infringing the '209 patent, actively inducing infringement of the '209 patent, and contributing to the infringement by others of the '209 patent, Lilly will suffer irreparable injury. Lilly has no adequate remedy at law.

90. An actual case or controversy exists between Lilly and APP with respect to infringement of the '209 patent.

COUNT V

(Patent Infringement – Pliva)

91. Lilly incorporates each of the preceding paragraphs as if fully set forth herein.

92. By letter dated March 19, 2009 ("Barr's Notice Letter"), Barr notified Lilly that it had submitted to the FDA ANDA No. 91-111 for Barr's Pemetrexed Disodium for Injection, Eq. 500 mg Base/Vial and Pemetrexed Disodium for Injection, Eq. 100 mg Base/Vial products ("Barr's ANDA Products"). Barr's ANDA Products are generic versions of ALIMTA®.

93. The purpose of ANDA No. 91-111 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Barr's ANDA Products prior to the expiration of the '932 patent. The expiration date of the '932 patent is earlier than the expiration date of the '209 patent.

94. In Barr's Notice Letter, Barr notified Lilly that Barr's ANDA Products contain pemetrexed disodium.

95. Upon information and belief, the use of Barr's ANDA Products in accordance with Barr's proposed labeling for Barr's ANDA Products involves administration of folic acid and vitamin B_{12}.

96. Upon information and belief, the use of Barr's ANDA Products in accordance with and as directed by Barr's proposed labeling for those products will infringe one or more claims of the '209 patent.

97. Barr's submission of ANDA No. 91-111 is for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA Products prior to the expiration of the '209 patent.

98. By letter dated September 16, 2010 ("Pliva's Notice Letter"), Pliva notified Lilly that, through its U.S. Regulatory Agent Teva USA, it had submitted to the FDA ANDA No. 091111 for Pliva's Pemetrexed Disodium Injectable, Eq. 100 mg Base/Vial and Eq. 500 mg Base/Vial ("Pliva's ANDA Products"). Pliva's ANDA Products are generic versions of ALIMTA®.

99. In the Pliva Notice Letter, Pliva also notified Lilly that, as part of its ANDA No. 091111, Pliva had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '209

patent. Upon information and belief, Pliva submitted ANDA No. 091111 containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '209 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of Pliva's ANDA Products. The submission of ANDA No. 091111 with such certifications for the '209 patent is an act of infringement of the '209 patent.

100. Upon information and belief, Pliva Hrvatska, Barr, and Teva USA are corporate affiliates and share a common direct or indirect parent company.

101. Upon information and belief, ANDA No. 91-111 and ANDA No. 091111 are the same ANDA.

102. Upon information and belief, Barr's ANDA Products are the same products as Pliva's ANDA Products.

103. In Pliva's Notice Letter, Pliva notified Lilly that Pliva's ANDA Products contain pemetrexed disodium.

104. Upon information and belief, the use of Pliva's ANDA Products in accordance with Pliva's proposed labeling for Pliva's ANDA Products involves administration of folic acid and vitamin B_{12}.

105. Upon information and belief, the use of Pliva's ANDA Products in accordance with and as directed by Pliva's proposed labeling for those products will infringe one or more claims of the '209 patent.

106. Pliva's submission of ANDA No. 091111 is for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Pliva's ANDA Products prior to the expiration of the '209 patent

107. Upon information and belief, Pliva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Pliva's ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 091111, *i.e.*, prior to the expiration of the '209 patent.

108. Upon information and belief, Pliva has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Pliva has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Pliva's ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 091111.

109. Upon information and belief, Pliva plans and intends to, and will, actively induce infringement of the '209 patent when ANDA No. 091111 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

110. Upon information and belief, Pliva knows that Pliva's ANDA Products are especially made or adapted for use in infringing the '209 patent, and that Pliva's ANDA Products are not suitable for substantial noninfringing use. Upon information and belief, Pliva plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 091111.

111. The foregoing actions by Pliva constitute and/or will constitute infringement of the '209 patent, active inducement of infringement of the '209 patent, and contribution to the infringement by others of the '209 patent.

112. Upon information and belief, Pliva is without a reasonable basis for believing that it will not be liable for infringing the '209 patent, actively inducing infringement of the '209 patent, and/or contributing to the infringement by others of the '209 patent.

113. Unless Pliva is enjoined from infringing the ’209 patent, actively inducing infringement of the ’209 patent, and contributing to the infringement by others of the ’209 patent, Lilly will suffer irreparable injury. Lilly has no adequate remedy at law.

114. An actual case or controversy exists between Lilly and Pliva with respect to infringement of the ’209 patent.

WHEREFORE, Lilly requests the following relief:

(a) A judgment that each of Teva, Teva USA, APP, and Pliva has infringed the ’209 patent and/or will infringe, actively induce infringement of, and/or contribute to infringement by others of the ’209 patent;

(b) A judgment ordering that

(i) the effective date of any FDA approval for Teva to make, use, offer for sale, sell, market, distribute, or import Teva’s 500 mg ANDA Product, or any product the use of which infringes the ’209 patent, be not earlier than the expiration date of the ’209 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(ii) the effective date of any FDA approval for Teva to make, use, offer for sale, sell, market, distribute, or import Teva’s 100 mg ANDA Product, or any product the use of which infringes the ’209 patent, be not earlier than the expiration date of the ’209 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(iii) the effective date of any FDA approval for Teva USA to make, use, offer for sale, sell, market, distribute, or import Teva's 500 mg ANDA Product, or any product the use of which infringes the '209 patent, be not earlier than the expiration date of the '209 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(iv) the effective date of any FDA approval for Teva USA to make, use, offer for sale, sell, market, distribute, or import Teva's 100 mg ANDA Product, or any product the use of which infringes the '209 patent, be not earlier than the expiration date of the '209 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(v) the effective date of any FDA approval for APP to make, use, offer for sale, sell, market, distribute, or import APP's 500 mg ANDA Product, or any product the use of which infringes the '209 patent, be not earlier than the expiration date of the '209 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(vi) the effective date of any FDA approval for APP to make, use, offer for sale, sell, market, distribute, or import APP's 100 mg ANDA Product, or any product the use of which infringes the '209 patent, be not earlier than the expiration date of the '209 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(vii) the effective date of any FDA approval for Pliva to make, use, offer for sale, sell, market, distribute, or import Pliva's ANDA Products, or any product the use of which infringes the '209 patent, be not earlier than the expiration date of the '209 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction

(i) enjoining Teva, and all persons acting in concert with Teva, from making, using, selling, offering for sale, marketing, distributing, or importing Teva's 500 mg ANDA Product, Teva's 100 mg ANDA Product, or any product the use of which infringes the '209 patent, or the inducement of or contribution to any of the foregoing, prior to the expiration date of the '209 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(ii) enjoining Teva USA, and all persons acting in concert with Teva USA, from making, using, selling, offering for sale, marketing, distributing, or importing Teva's 500 mg ANDA Product, Teva's 100 mg ANDA Product, Pliva's ANDA Products, or any product the use of which infringes the '209 patent, or the inducement of or contribution to any of the foregoing, prior to the expiration date of the '209 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(iii) enjoining APP, and all persons acting in concert with APP, from making, using, selling, offering for sale, marketing, distributing, or

importing APP's 500 mg ANDA Product, APP's 100 mg ANDA Product, or any product the use of which infringes the '209 patent, or the inducement of or contribution to any of the foregoing, prior to the expiration date of the '209 patent, inclusive of any extension(s) and additional period(s) of exclusivity; and

(iv) enjoining Pliva, and all persons acting in concert with Pliva, from making, using, selling, offering for sale, marketing, distributing, or importing Pliva's ANDA Products, or any product the use of which infringes the '209 patent, or the inducement of or contribution to any of the foregoing, prior to the expiration date of the '209 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing of

(i) Teva's 500 mg ANDA Product;

(ii) Teva's 100 mg ANDA Product;

(iii) APP's 500 mg ANDA Product;

(iv) APP's 100 mg ANDA Product; and

(iv) Pliva's ANDA Products;

or any product the use of which infringes the '209 patent, prior to the expiration date of the '209 patent, infringes, will infringe, will actively induce infringement of, and/or will contribute to the infringement by others of the '209 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Lilly's costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Respectfully submitted,

/s/ *Jan M. Carroll*

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